MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Ronald Reagan Building
International Trade Center
Horizon Ballroom
1300 13th Street, N.W.
Washington, D.C.

Friday, October 19, 2001
9:00 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
ROBERT D. REISCHAUER, Ph.D., Vice Chair
AUTRY O.V. "PETE" DeBUSK
ALLEN FEEZOR
FLOYD D. LOOP, M.D.
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JOSEPH P. NEWHOUSE, Ph.D.
JANET G. NEWPORT
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JOHN W. ROWE, M.D.
DAVID A. SMITH
RAY A. STOWERS, D.O.
MARY K. WAKEFIELD, Ph.D.

Agenda item:
Public comment

MR. HACKBARTH: Okay, public comment period now begins. Any comment from those in the audience?

MS. SHULMAN: I'm Rosalyn Shulman with the American Hospital Association. The AHA wants to thank the MedPAC commissioners and staff for their attention to regulatory reform and relief as well as blood costs. The regulatory reform and relief issue has been an important one for our membership, as evidenced by the PricewaterhouseCoopers study on patients and paperwork that we made available to MedPAC commissioners. We look forward to working with you to achieve regulatory reform.

Regarding blood, the AHA is committed to the continued safety of America's blood supply and believes it to be a critical factor in providing high quality care. New technologies have helped us to improve blood safety. But of course, this has led to inreased blood prices as well. Unfortunately, blood price increases have not been adequately captured in the Medicare marketbasket or by MedPAC's update process.

Hospital blood costs have inreased significantly in recent years due to a number of factors that are intended to bolster the safety of the nation's blood supply, including numerous screening tests and confirmation tests mandated by FDA as well as blood donor deferral requirements intended to protect against variant CJD as well as other requirements.

But blood prices have also risen dramatically due to things other than FDA mandates. For instance, the American Red Cross, which supplies one-half of the blood used by hospitals, recently changed its policies so that hospitals will only be able to purchase leuko-reduced red blood cells. This increases, as we understand it, the per-unit cost by about $30 to $40. This is not a change just in price, it's actually a change in product.

This and other policy change by the American Red Cross have resulted in an average 35 percent increase in the pricce of blood. However, as staff mentioned, many of our members are reporting much higher increases than that; increases as high as 80 percent of 100 percent.

The price of blood is expected to increase even more in the near future as new screening tests are formally mandated by FDA. Nucleic acid testing, or NAT, is one example of such a new technology. NAT testing costs $8 to $10 per pint of blood. Once NAT testing is fully licensed by FDA we expect the price for this test to double. The price will increase even more if FDA requires that individual testing replace current pooled testing.

Viral inactivation is a technique under development that holds a great deal of promise, but it is expected to increase, double or triple the price of blood.

Further, the FDA recently indicated their intent to put into place a stricter donor deferral policy in the next year which will drive costs even higher. The American Red Cross' donor deferral policy instituted this month is even more strict than the FDA's proposed policy.

So consistent with comments that were made today by MedPAC staff and commissioners, the AHA believes that the fact that the Medicare hospital marketbasket does not include an explicit measure of blood price fluctuation means that inreases in the price of blood are not appropriately accounted for in Medicare payments to hospitals. Therefore, the AHA strongly urges the Commission to recommend that CMS revise the marketbasket index to include an appropriately weighted blood and blood product PPI.

In addition, any advancement in blood screening and processing technology that is not captured in the PPI needs to be explicitly considered for the S&TA adjustment process. In this way, Medicare payment policy will finally support the public health imperative of a safer blood supply.

Thanks.

MR. HALL: Good morning. My name is Stephan Hall. I'm with the Advanced Medical Technology Association formerly known as HEMA. I'm accompanied today by Guy King, formerly chief actuary at HCFA who's helped us prepare our comment today.

First of all I wanted to commend the MedPAC staff for their very diligent work in preparing this report, and very thorough consideration of the issues. I wanted to share with you just some key points of the written statement that we provided to this commission.

AvMed fully supports a careful review and revision of the Medicare payment methodologies to help ensure that there's adequate reimbursement for safe blood products. We strongly support the use of a separately-weighted producer price index for blood products, with an appropriate weighting factor in addition, in the annual marketbasket index calculation by CMS.

However, we do not think this is the only remedy that this body nor CMS should consider. We think there are other steps that ought to be taken, including potentially improvements in coding and examination of the billing behavior by hospitals. That would help ensure that the full cost of providing transfusions are captured in our system and appropriately reflected in the annual recalibration process.

I won't review at length the factors that contribute to blood costs because many of them have just been mentioned, but I would like to mention the unique economics of the blood collection market. The first point to share there is that this is a predominantly non-profit collection market. That is, the entities who produce the blood products for sale to hospitals operate on a not-for-profit basis.

At the same time, the markets for blood products are extremely competitive and hospitals with narrow budgets can be extremely sensitive to changes in the prices of the blood products they purchase. This price sensitivity can lead hospitals to struggle in purchasing safer technology-enhanced blood products.

Further still, there may be delays in the pricing adjustments by the non-profit blood collectors to reflect the cost of producing the blood. There may be a lag in the market price that a hospital pays. I don't have concrete evidence to demonstrate this, but we did do an analysis of data, which I'll

mention in a minute, that showed costs among 35 community blood centers as compared to the producer price index that's currently released by the Bureau of Labor Statistics.

This phenomena of costs being greater than prices may be particularly acute when there are new regulatory requirements or new safety mandates that public health concerns demand for adoption by the blood collectors. There's also anecdotal evidence that hospitals, once they have purchased blood units, do not bill and charge for technology-enhanced blood products in a fashion that's consistent with the way in which other services are billed.

For tehse reasons, the economics of producing safe blood products is very complex and does not follow the same pricing and purchasing patterns as other technology-enhanced items. So one could imagine a first loop before the DRG reweighting loop occurs in which prices are delayed by several years before they are updated to reflect actual costs.

As mentioned earlier, medical technologies are a critical element in blood safety, and over the past decade they've made significant contributions to the safety of our blood supply. They're employed in virtually all aspects of collection, processing, distribution, and utilization of blood products. These are driven by both regulatory requirements by the FDA, but also, importantly, voluntary adoption of technologies by blood collectors who see a moral and ethical imperative to improve the quality of the blood supply, and also are responding to patient demand.

Ensuring blood safety obviously involves extensive costs. Here I'd like to mention the survey of 35 community blood centers which spanned a five-year period from 1996 to the year 2000. I was interested to hear that Tim Green's analysis of the cost report data showed no difference between the costs -- I believe he said this -- the cost of purchasing blood and the annual update factor. That is not what we found.

We found that the cost of producing blood units in this sample rose at an average annual rate of 7 percent between 1996 and the year 2000. This obviously doesn't reflect the recent price increases that have been observed by the American Red Cross this year.

When you break down the different activities of blood centers, collection and testing account for 31 and 21 percent of the cost of producing a unit of blood. The rate of increase for these various activities has been most dramatic for testing and production of blood components which rose by 44 and 57 percent, respectively, over a five-year period.

So that brought us to the producer price index and an examination of whether or not it was a reliable measure of the cost of producing blood. We noticed that there is a dramatic jump btween 1997 and 1999 in the PPI that exists for blood products. That average annual rate is 5.1 percent of icnrease. So rather than this being a one-year spike in the prices of blood, we believe it represents a five-year upward trend in the prices of these blood products. The trends between the PPI data and our cost data from the 35 blood centers appeared to be

roughly similar, although we noted that the prices tended to lag by a least a year the cost trends that we observed.

As mentioned before, since 1996 the PPI for blood and derivatives has been subsumed within the PPI for chemicals. We note that that has risen at a far slower rate than the PPI for blood. I think it was 1.5 percent as compared to 5 percent.

We also compared this trend to the rate of Medicare funding and we found that the 7 percent for our cost data far outpaced the increases in Medicare inpatient input price index, which rose at an average annual rate of only 2.8 percent in this timeframe, and the inpatient hospital update factor increased at an average annual rate of only 0.9 percent. So our cost data was literally seven times greater than the update factors increases during the same time period.

I'll just, to wrap up my comments, mention that there are a number of future technologies that will address other concerns in the blood supply. These are in development. They include nucleic acid testing, pathogen elimination, additional infectious disease testing, additional processes for interviewing donors and screening them, as well as blood substitute products and enzymatic conversion of red cells. All of these technologies will contribute further to addressing the concerns that we know of today. Obviously that's a moving target. There will be future concerns that result in technology solutions and additional costs in order to ensure the safety of the blood supply.

To conclude, we fully support the use of a separate PPI for blood and blood derivatives. We have not yet considered the second option that was presented by Tim Greene today. We think it's intriguing. It's something we would look at. We don't oppose the use of an add-on for the update factor. Although it is not something we've included in our comments, we will be looking at it between now and November when this commission reconvenes on this issue.

Thank you.

MS. BRODY: I'm here to talk about blood. My name is Lisa Marie Brody. I'm the director of government affairs for America's Blood Centers. America's Blood Centers, or ABC, is a national network of 75 not-for-profit community-based blood centers which provide nearly half the nation's blood supply to over 3,100 hospitals. America's Blood Centers are located in 45 states and we serve roughly about 125 million people at 450 donation sites.

As non-profit or not-for-profit organizations, America's Blood Centers members pass the cost of collecting, processing, testing, and distributing blood to hospitals. Our members have always prided themselves and worked diligently on providing the highest service at the lowest cost to the hospitals and patients that they serve.

Blood transfusions save over 4 million lives each year. The cost of these transfusions is roughly about $4 billion annually, or less than 2 percent of America's inpatient health care costs. About half of these costs are for providing blood and ensuring its safety, and the other half are hospital costs to ensure blood

compatibility and that compatible blood is transfused to the right patient.

While America's blood bill is less than 2 percent of the total, lifesaving transfusions support over 30 percent of all inpatient treatments. This includes organ and marrow transplants, cancer therapies and surgery, trauma and reconstructive surgery.

The blood community along with Congress and the American public demand a safe and available blood supply. In response, new technologies and tests and donor deferrals to improve blood safety are being developed or have already been implemented and recommended by the Food and Drug Administration. These new safety measures, however, are costly and have not been adequately addressed under the current inpatient payment system administered by HCFA. The result is a safe blood supply that has not been paid for.

The majority of blood and blood products are reimbursed under the DRG system. Because the DRGs are re-based only every five years and blood is not included in the yearly marketbasket updates and technology adjustments, the sysetm is inadequate to meet the rapidly changing cost associated with blood safety. The addition of new, costly safe technologies and tests such as leuko-reduction and nucleic acid testing have also not been accounted for in the relatively modest DRG increases over the last five years.

Safety is not the only problem with payment. We are currently experiencing an ever increasing supply problem. Blood is a unique commodity in the sense that it requires people to actually donate. You can't produce blood. People have to be willing to donate blood. So to make sure that the blood is there when it's needed will require investment of millions of dollars in research, paid advertising, new blood collection infrastructure such as buses and staffing, and other outreach to bring in new donors to replace those lost, and encourage current donors to provide blood more often.

Yet the non-profit industry of the blood-banking community has no capital to reinvest. So our only recourse is to raise fees to hospitals. But because hospitals aren't properly reimbursed for blood we can't really raise our prices. Our hospital customers have traditionally been resistant to pay increased prices for blood.

In the testimony that I provided and we'll be giving to all of you we have attached some timelines which will associate the cost of blood over time and provide relevant data about the different costs and how that cost has been filtered down to the blood-banking community. I won't go into those.

The cost associated with providing a safe and available blood supply was looked at and addressed in the outpatient system. As the outpatient prospective system now recognizes, new blood safety measures have dramatically increased the cost of blood. Our hope is that the recent steps taken by HCFA to make reimbursement for blood more responsive to cost increases in the outpatient setting will now be replicated in the inpatient setting where the vast majority of blood transfusions take place.

America's Blood Centers believes it's really critical that adequate reimbursement and quality of care must be representative and consistent in both settings.

As I stated, HHS through the Food and Drug Administration, agrees with the blood community that these new technologies to further blood safety should be implemented. But the question still remains is how to pay for them. When FDA recommends or implements a new blood safety measure, hospitals often wait two to three years before receiving proportionate reimbursement increases from Medicare and Medicaid. This is not trivial since only 50 percent of all transfusions go to patients covered by Medicare and Medicaid.

In addition, private payers usually follow Medicare's lead on reimbursement levels. Lack of adequate reimbursement for blood products has placed an inordinately heavy financial burden on blood centers and hospitals.

MR. HACKBARTH: I'm going to interrupt you here. I want to make sure that other people in the audience, perhaps on different topics altogether, have an opportunity. Thanks for your statement. We welcome the contribution.

Other people?

Okay, we adjourn until our November meeting which is when? I didn't mean to ask a difficult question.

DR. ROSS: Good question. The 15th and 16th.

MR. HACKBARTH: The 15th and 16th. Thank you to all the staff for all the work, both on the presentations and the facilities and logistics.

[Whereupon, at 12:12 p.m., the meeting was adjourned.]